

U.S. Patent Appl. N . 09/825,293

Attorney Docket No: 021123-0280108

II. REMARKS

Preliminary Remarks

Reconsideration and allowance of the present application based on the following remarks are respectfully requested. Claims 20-45 are currently pending in this application. Claims 37, 38, 44, and 45 have been withdrawn from consideration as allegedly being directed to an invention that is independent or distinct from the invention originally claimed. Claims 27, 35, and 36 have been allowed. Claims 20-26, 28-34, and 39-43 remain at issue. This response is timely filed. Should the Patent Office determine that additional fees are required for consideration of this response, permission is hereby granted to charge such fees to Deposit Account No. 033975.

In paragraph three of the official action, the examiner objected to claims 23-26 and 28-31 as allegedly expanding the scope of claims 20 and 27, respectively. The examiner requested the applicants rewrite the claims in independent form. Solely for the purpose of expediting prosecution, and without prejudice to the applicants' right to seek broader claims in a continuing application, the applicants have canceled claimed 23-26 and 28-31. Accordingly, the applicants request withdrawal of the objection to claims 23-26 and 28-31.

On the Office Action Summary sheet of the official action, claims 42 and 43 appear to be rejected, but the applicants were unable to locate which rejection (or rejections) applied to claims 42 or 43. The applicants respectfully request clarification whether an outstanding rejection exists for claims 42 and 43.

The applicants do not intend by these or any amendments to abandon the subject matter of the claims as originally filed or later presented, and reserve the right to pursue such subject matter in continuing applications. The applicants request entry of the foregoing amendment in that the amendments overcome the present rejection or in the alternative, place the application in better form for allowance.

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Patentability Remarks

Rejection Pursuant 35 U.S.C. §112, First Paragraph

Enablement

In paragraph 5 of the official action, the examiner rejected claims 23-26, 28-34, and 39 under 35 U.S.C. 112, first paragraph, for allegedly failing to comply with the enablement requirement. Specifically, the examiner alleged the nature and breadth of the claims encompassing any polynucleotide encoding a protein with an amino acid sequence that is at least 70-95% identical to that of SEQ ID NO: 2 or any isolated polynucleotide that is at least 70-95% identical to that of SEQ ID NO: 1 is not enabled. The examiner asserted the specification does not provide guidance with respect to the specific binding/catalytic amino acids and the structural motifs essential for protein/enzyme structure and activity. The examiner concluded that to make the claimed invention is well outside the realm of routine experimentation and predictability in the art since there is no information in the specification regarding the specific binding/catalytic amino acids and the structural motifs essential for protein structure and activity function.

Solely for the purpose of expediting prosecution, and without prejudice to the applicants' right to seek broader claims in a continuing application, the applicants have canceled claims 23-26, and 28-31. Dependent claims 32-34, and 39 are now directed to vectors and host cells harboring nucleic acids that are fully enabled by the teachings of the specification. In view of the foregoing amendment, the applicants request that the rejection of claims 23-26, 28-34, and 39 under 35 U.S.C. §112, first paragraph, for lack of enablement is moot, and should be withdrawn.

Written Description

In paragraph 6 of the official action, the examiner rejected claims 23-26, 28-34, 39, 40, and 41 under 35 U.S.C. §112, first paragraph, for allegedly lacking written descriptive support in the specification. Specifically, the examiner alleged the applicants' arguments filed June 13, 2002 were not persuasive because the specification only provides a description of a polynucleotide comprising the nucleotide sequence of SEQ ID NO: 1, and does not describe additional representative polynucleotide species (% variants or polynucleotides that hybridize to the complement of SEQ ID NO: 1). The examiner further alleged that the specification fails to describe these additional variant or hybridization polynucleotide species

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because the structural characteristics or properties are not apparent from the teachings of the specification. The examiner concluded that the applicants have failed to sufficiently describe the claimed invention in full, clear, concise, and exact terms that a skilled artisan would recognize that the applicants were in possession of the claimed invention.

As discussed above, claims 23-26 and 28-31 have been canceled without prejudice, and claims 32-34 and 39 are now directed to vectors and host cells harboring nucleic acids fully described in the specification. Amended claims 40 and 41 are now directed to an isolated polynucleotide that hybridizes under stringent conditions to the complement of SEQ ID NO: 1, and has the same biological activity as the transcriptional regulator Mike17 wherein said stringent conditions comprise washing in 0.5X SSC or 0.1X SSC at a temperature of 68°C. The applicants submit the specific hybridization conditions recited in amended claims 40 and 41 are described in the original specification on page 9, line 16 to page 10, line 13. These wash conditions are stringent and thus would not allow for any polynucleotide to hybridize to the complement of SEQ ID NO: 1. In fact, amended claims 40 and 41 recite hybridization conditions wherein only those nucleic acids that can hybridize to SEQ ID NO: 1 at 0.1 or 0.5X SSC at 68°C and encode a protein with the same biological activity as the transcriptional regulatory Mike17 fall within the scope of the claims. This population of nucleic acids are well described in the specification to enable one of skill in the art to recognize the applicants were in possession of the claimed invention. In view of the foregoing amendment and remarks, the applicants submit the rejection of claims 23-26, 28-34, 39, 40, and 41 under 35 U.S.C. §112, first paragraph, for allegedly lacking written descriptive has been overcome, and should be withdrawn.

Rejection Pursuant 35 U.S.C. §112, Second Paragraph

In paragraph 8 of the official action, the examiner rejected claims 20 and 21 under 35 U.S.C. §112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter the applicants regard as the invention. Specifically, the examiner asserted the phrase "may be used" in claim 20 is unclear because it is not known how the claimed polynucleotide by itself can increase the production of amino acids. The examiner asserted claim 21's phrase "degenerate variants thereof" is not clear.

By removing the phrase "may be used," amended claim 20 is now directed to an isolated polynucleotide encoding a protein with an amino acid sequence comprising the sequence as set forth in SEQ ID NO: 2. Amended claim 21 is directed to an isolated

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polynucleotide consisting of nucleotides 252-1673 of SEQ ID NO: 1 and fragments thereof, thereby removing the phrase "degenerate variants thereof." In view of the foregoing amendments, the applicants respectfully submit that the rejection of claims 20 and 21 pursuant to 35 U.S.C. §112, second paragraph, for being indefinite, is overcome and should be withdrawn.

Rejection Pursuant 35 U.S.C. §102

Reeves et al.

In paragraph 10 of the official action, the examiner rejected claim 21 under 35 U.S.C. §102(b) as allegedly being anticipated by Reeves *et al.*, GenBank Accession No. AAA14663 (hereafter Reeves *et al.*). Specifically, the examiner alleged Reeves *et al.* teach a polynucleotide "consisting essentially of nucleotides 252-1673 of SEQ ID NO: 1."

Amended claim 21 is directed to an isolated polynucleotide consisting of nucleotides 252-1673 of SEQ ID NO: 1 and fragments thereof. Reeves *et al.* neither teach or suggest the SEQ ID NO: 1 fragment 252-1673 as evidenced by the sequence alignment which indicates only a 44.7% similarity and 463 base pair mismatches of the 1421 total base pairs for this fragment. In view of the foregoing amendment and remarks, the rejection of claim 21 pursuant to 35 U.S.C. §102(b) has been overcome, and should be withdrawn.

Murdin et al.

In paragraph 11 of the official action, the examiner rejected claim 22 under 35 U.S.C. §102(b) as allegedly being anticipated by Murdin *et al.*, GenBank Accession No. AAZ61503. Specifically, the examiner alleged Murdin *et al.* teach a polynucleotide encoding a protein "consisting essentially of the amino acid of SEQ ID NO: 2."

Amended claim 22 is directed to an isolated polynucleotide consisting of nucleotides encoding a protein consisting of the amino acid sequence SEQ ID NO: 2. Murdin *et al.* do not teach the amino acid sequence of SEQ ID NO: 2. In fact, Murdin *et al.* are only 21% identical to SEQ ID NO: 2. In view foregoing amendment and remarks, the rejection of claim 22 pursuant to 35 U.S.C. §102(b) has been overcome, and should be withdrawn.

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Schauwecker et al.

In paragraph 12 of the official action, the examiner rejected claims 40 and 41 under 35 U.S.C. §102(b) as allegedly being anticipated by Schauwecker *et al.*, Accession No. AAF25795. Specifically, the examiner alleged Schauwecker *et al.* teach a polynucleotide that is expected to hybridize to SEQ ID NO: 1 since the claim is not limited to the stringent hybridization temperature of 68°C.

Amended claims 40 and 41 are directed to an isolated polynucleotide which hybridizes under stringent conditions to the complement of SEQ ID NO: 1, and have the same biological activity as the transcriptional regulator Mike17 wherein said stringent conditions comprising washing in 0.5 or 0.1X SSC at a temperature of 68°C. As suggested by the examiner on page 6 of the official action, the nucleic acids of Schauwecker *et al.* would not hybridize to the nucleic acids of amended claims 40 and 41 under the stringent hybridization conditions of 0.1 or 0.5X SSC at a temperature of 68°C. In view of the foregoing amendment and remarks, the rejection of claims 40 and 41 pursuant to 35 U.S.C. §102(b) in view of Schauwecker *et al.* has been overcome and should be withdrawn.

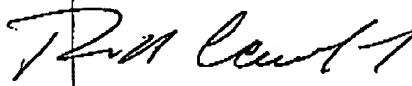
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III. CONCLUSION

In view of the foregoing, the claims are now believed to be in form for allowance, and such action such action is hereby solicited. If any point remains in issue which the examiner feels may be best resolved through a personal or telephone interview, please contact the undersigned at the telephone number listed below.

Respectfully submitted,
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